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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,968	04/20/2001	Michael B. Foster	RENAS/03	1662

7590 12/02/2002

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	10

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,968	FOSTER, MICHAEL B.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The finality of the previous office action (Paper No. 6) is withdrawn because a new ground of rejection is applied in this office action.

Status of the Claims

2. Claims 1-11, 13-16 and 18 are pending.

Applicants' amendment filed on September 23, 2002 (Paper No. 7) has been entered, and applicants' response has been fully considered. Claims 1, 2, 10, 11 and 15 have been amended, and claims 12, 17 and 19 have been cancelled. Thus, claims 1-11, 13-16 and 18 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1-18 under 35 U.S.C. 112 second paragraph, regarding the term "an agent consisting essentially of" or "about", is withdrawn in view of applicants' cancellation of the claim and applicants' response at pages 4-5 in Paper No. 7.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1, 4-10, 12-14, 18 and 19 under 35 U.S.C. 102(b) as being anticipated by Chein (U. S. Patent 5,855,920), is withdrawn in view of applicants' cancellation of the claim and applicants' response at pages 6-7 in Paper No. 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 3, 7, 10, 11, 13, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 2, 3, 11, 15 and 16 are indefinite because of the use of the term "said maintenance dose is calculated from a daily dose to a monthly dose based on individualized bioavailability data" or "said dose producing said optimal response is calculated from a daily dose to a monthly dose based on individualized bioavailability data". The cited term renders the claim indefinite, it is unclear what is an individualized bioavailability data, and how the maintenance dose, which is a daily dose, can be calculated from a daily dose to a monthly dose based on the individualized bioavailability data. Claims 3 and 16 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

7. Claim 7, for example, is indefinite because of the use of the term "insulin like growth factor levels". The cited term renders the claim indefinite, it is unclear which insulin like growth factor is increased. Use of "insulin like growth factor-1 levels" is suggested. See also claim 13.

8. Claims 10, 11 and 13 are indefinite because the claim does not cite the step of "administering said dose producing said optimal response as a maintenance dose". Claims 11 and 13 are included in this rejection for being dependent on rejected claims and not correcting the deficiency of the claims from which they depend.

9. Claim 11 recites the limitation "said dose producing said optimal response" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 4, 7-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Drake *et al.* (J. Clinical Endocrinology 47, 571-581 (1997)).

Drake *et al.* teaches a method for optimizing growth hormone replacement therapy in hypopituitary adult; the method comprising determining the levels of insulin-like growth factor-1 (IGF-1; claims 7 and 13) or IGF binding protein 3 (IGFBP-3) in response to an initial dose (0.8 or 0.4 IU daily) of hGH (Genotropin, claims 1 (step 1) and 4), adjusting the dose of hGH until serum level of IGF-1 between the median and the upper end of the age-related reference range is achieved (claim 1 (steps 2 & 3)), establishing the dosage of hGH needed to maintain target IGF-1 levels, and administering the established dose of hGH (Claims 1 (step 4) and 10; page 3914; Fig. 1). The initial dose of 0.8 or 0.4 IU daily (1 IU = 330 μg) corresponds to 5.5 or 2.8 μg/day/kg for female (assuming 48 kg), which is about 4 μg/day/kg (claim 9), or, 3.8 or 1.9 μg/day/kg for male (assuming 70 kg), which is about 2 μg/day/kg (claim 8).

11. Claims 1, 4-10, 13, 14 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Murray *et al.* (Clinical Endocrinology 52, 537-542 (May 2000)).

Murray *et al.* teaches using an individualized low-dose titration regimen for a growth hormone replacement therapy in adult with GH deficiency; the method comprising determining

the levels of insulin-like growth factor-1 (IGF-1; claims 7 and 13) in response to an initial dose (0.8 IU daily) of hGH (Genotropin, claims 1 & 14 (step 1), 4 and 18), adjusting the dose of hGH by 0.2 or 0.4 IU/day increments until serum level of IGF-1 reaches in the range of the age-related mean for the normal population (claims 1 & 14 (steps 2 & 3); page 538), establishing the dosage of hGH needed to maintain target IGF-1 levels, and administering the established dose of hGH (claims 1 (step 4) and 10; page 539; Table 1). The initial dose of 0.8 IU daily (1 IU = 330 μg) corresponds to 5.5 μg/day/kg for female (assuming 48 kg), which is about 4 μg/day/kg (claim 9), or, 3.8 μg/day/kg for male (assuming 70 kg), which is about 2 μg/day/kg (claim 8). The median value of the maintenance dose for female is 1.6 IU/day (range 0.4-2.4), which corresponds to 11 μg/day/kg (range 2.8-17; page 539; claims 6 and 14 (step 4)). The median value of the maintenance dose for male is 0.8 IU/day (range 0.4-2.0), which corresponds to 3.8 μg/day/kg (range 1.9-9.4), the maintenance dose of 9.4 μg/day/kg is about 10 μg/day/kg (claim 5) absent definition in the specification.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

November 29, 2002

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